

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

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DOUGLAS J. HORN and CINDY HARP-HORN,

Civ Action No: 15-cv-701 FPG/MJR

Plaintiff,

-against-

MEDICAL MARIJUANA, INC.,
DIXIE ELIXIRS AND EDIBLES,
RED DICE HOLDINGS, LLC, and
DIXIE BOTANICALS,

Defendants,
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***PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO
DEFENDANTS' MOTION FOR REVISION and
IN SUPPORT OF PLAINTIFF'S CROSS-MOTION FOR SAME***

This case involves the defendants manufacture, sale and distribution of a now proven illegal¹ product that was purchased by the plaintiff and plaintiff's subsequent use to the product led directly to his termination from the lucrative trucking job he held for a period of years.

Defendant's Motion For Reconsideration, filed July 17, 2019, contends that "it was a genuine error for the Court to find that Dixie X contained 'resin extract derived from the Cannabis sativa plant'. See ECF 97-1, at 1, quoting from Order, ECF No. 88 at 24. Defendants assert: "[I]t is not even possible to extract 'resin' from the stalks of hemp Cannabis sativa plants, which is undisputedly, the manner in which the CBD was extracted from the plants in order to formulate the Dixie X product." See ECF No. 97-1 at 4, quoting ECF No. 97-1 at 17. Remarkably, the Defendants do not counter the Court's statement or offer any explanation as to what precisely is the source of their extracted product.

¹ Illegal by virtue of the Dixie Elixir's proven THC content.

Annexed immediately hereto is the Affidavit of plaintiff's expert and Forensic Toxicologist Dr. Kenneth Graham, Ph.D. In his Affidavit, Dr. Graham explains this scientifically specific issue as it relates to the federal law which regulates defendants' manufacture and distribution of the THC-containing product at issue in this industry. He illustrates how the defendants' motion is misguided in that it is immaterial whether the plant compound used to describe the formulation basis of the Dixie product was obtained from a resin extract or a non-resin extract.

In contrast, the Court should respectfully note that Defendants' motion offers no competing scientific inquiry or explanation to support why or how the Dixie product would warrant an exemption under the Controlled Substances Act. Clear on the face of defendants' Dr. Titus' Declaration:

"Upon information and belief, the Dixie X product that Douglas Horn purchased and allegedly consumed in 2012 did not contain "resin extracted from" the Cannabis sativa plant." (Emphasis added, and in the original.)

What undisclosed "information and belief" is Dr. Titus referring to? This motion by Defendants is, in its essence, a *second* Motion for Summary Judgment on an issue for which Defendants clearly have exclusive information, did not raise on the underlying motion, and offered no new evidence to prove their point, save the bald and conclusory claims of its CEO.

Nonetheless, as shown in plaintiff's expert Dr. Graham's Affidavit annexed hereto, Defendants attempt to make a distinction without a difference, or even relevance. Despite the defendants' apparent effort to convolute the simple issue of the proven content of THC in the product plaintiff took, the law has not changed with respect to the illegality of defendants practice in 2012, when it affected plaintiff, and going forward.

Any Product That Contains THC Is A Schedule I Controlled Substance.

The substances Defendants extracted from the cannabis plant in 2012 are what matters, not the specific form of the extract involved. A variety of terms are used, throughout the court record, to refer to the raw ingredients used to make Dixie X: a “resin extract”², a “hemp paste”³, “an extract derived from medicinal hemp”⁴, “the raw plant”⁵, “a very, very, very viscous, think honey, kind of material”⁶, or “hemp whole plant extract”, as emblazoned on the Dixie X label.

The inescapable fact is that any product that contains any amount of THC was a Schedule I controlled substance in 2012.

Schedule I of the CSA is amended periodically⁷, as the Court noted in his analysis of two 9th Circuit cases, *Hemp Industries Assoc. v. DEA*, 333 F.3d 1082 (9th Cir.2003) (“*Hemp I*”) and *Hemp Industries Assoc. v. DEA*, 357 F.3d 1012 (9th Cir.2004) (“*Hemp II*”). In 2003, the CSA was amended with 21 CFR 1308 DEA 205F⁸. See Federal Register, Vol. 68, No. 55, Friday, March 21, 2003, Rules and Regulations (attached hereto). DEA 205F clarifies the exemption from schedule I of products, such as hemp, derived from cannabis. DEA 205F states: “This rule does not change the legal status of so-called “hemp” products (products made from portions of the cannabis plant that are excluded from the CSA definition of marijuana). Rather, this rule clarifies provisions of the law and regulations that have been in effect since 1971. For the reasons provided in the interpretive rule, it is DEA’s view that the CSA and DEA regulations have always (since their enactment more than 30 years ago) declared any product that contains

² ECF No. 88 at 24.

³ See ECF 61-9 at page 96, testimony of Defendant’s expert Cindy Orser.

⁴ Id at 103.

⁵ Id at 97.

⁶ Id at 105.

⁷ The CSA, specifically 21 U.S.C. 811, 812 of Rule 21 CFR 1308, authorizes the Attorney General to publish amendments to the schedules in the Code of Federal Regulations. The Attorney General delegates the CSA amendment function to the Drug Enforcement Administration (DEA). DEA rules have the full force of law and are binding on the courts.

⁸ Codified as 21 CFR 1308.11(d)(27).

any amount of tetrahydrocannabinols to be a schedule I controlled substance. This interpretation holds regardless of whether the product in question is made from “hemp” or any other material.” See Federal Register, Vol. 68, No. 55, March 21, 2003, page 14115.

DEA 205F made clear that there was no loophole in the law for any part of the cannabis plant that contains THC. “[T]o treat natural THC as a noncontrolled substance would provide a loophole in the law that might be exploited by drug traffickers. If natural THC were a noncontrolled substance, those portions of the cannabis plant that are excluded from the CSA definition of marijuana (the stalks and sterilized seeds of the plant) would be legal, noncontrolled substances—regardless of their THC content. As a result, it would be legal to import into the United States, and to possess, unlimited quantities of cannabis stalks and sterilized seeds—again, regardless of their THC content. Anyone could then obtain this raw cannabis plant material to produce an extract of THC—all without legal consequence. This would give drug traffickers an essentially limitless supply of raw plant material from which they could produce large quantities of a highly potent extract that would be considered a noncontrolled substance and, therefore, entirely beyond the reach of law enforcement. To provide such a safe harbor to drug traffickers would be plainly at odds with the purpose and structure of the CSA.” *Id.* At 14114.

As Plaintiff’s expert explains, whether or not Dixie X is derived from a resin extract, the Defendants’ product cannot be excluded from the CSA definition of marijuana because any product that contains any amount of THC is a schedule I controlled substance.

Furthermore, the Hemp I and Hemp II appellants, manufacturers of hemp-based products, argued that their product was made from the “mature stalks” or the “oil and cake made from the seeds” of the Cannabis plant”. *Id.* (Hemp II) at 1018. The Defendants here make a much narrower argument. Defendants insist merely that their product was not extracted from resin.

Nowhere do these Defendants assert that only the mature stalks and sterilized seeds of the cannabis plant are used in producing Dixie X. Indeed, the product label reads “hemp whole plant extract”. The report of Dr. Cindy Orser, See ECF 61-9 at page 2, states: Dixie...extracted the CBD from the plant stalks...”. Dr. Orser did not use the word “mature” or “seed” during her deposition.

Elixirs For Oral Consumption Not Exempt From CSA.

Even if, *arguendo*, Dixie X were derived from parts of the cannabis excluded from the CSA, which Defendants have neither argued nor proven, because Dixie X was marketed as an “elixir” to be taken *orally*, it runs afoul of the CSA as amended by 21 CFR 1308 DEA 206F⁹. See Federal Register, Vol. 68, No. 55, Friday, March 21, 2003, Rules and Regulations, page 14119 (attached hereto). This rule established that cannabis-derived products with trace amounts of THC may be excluded from CSA control “provided they are not used, or intended for use, for human consumption (and therefore cannot cause THC to enter the human body).”

Two facts are beyond dispute, Dixie X was formulated, marketed and distributed for human consumption and it contained THC. The Defendants’ internal contemporaneous chemical analysis showed measurable levels of THC in it’s Dixie X product, see ECF 60-14 and ECF 60-10.. These facts together made the Dixie X Elixir violative of the CSA under § 1308.35.

Burden Of Proof Is On Defendants

Plaintiffs respectfully submit that it is irrelevant whether Dixie X was made from the excluded parts of cannabis, i.e. the mature stalks and sterilized seeds, or from extracted resin, the CSA exclusion. Despite that it is their burden to prove that the product they marketed and sold

⁹ Codified as 21 CFR 1308.35

was exempt from the CSA's definition of marijuana, the Defendants virtually ignore the point, failing to argue either way.

Rule 206F provides that, "In any proceeding arising under the Act or this chapter, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this section shall be upon the person claiming such exemption, as set forth in section 515(a)(1) of the Act (21 U.S.C. 885(a)(1)). In order to meet this burden with respect to a product or plant material that has not been expressly exempted from control by the Administrator pursuant to Sec. 1308.23, the person claiming the exemption must present rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans."

The dearth of evidence adduced by Defendants on the composition of Dixie X can be attributed to the lack of genuine dispute about it. As the Court observed, "there are sufficient facts from which it can be inferred that Defendants knew the identity of the substance they possessed." See ECF No. 88 at 10.

Congress Intended To Outlaw All Plants Containing THC.

In 1993, the Second Circuit federal court heard an appeal brought by an offender who was sentenced to five years for growing marijuana on his land in upstate New York. *U.S. v. Proyect*, 989 F.2d 84 (2nd Cir. 1993). Defendant Joel Proyect appealed his sentence arguing that only *female* marijuana plants should be counted toward the 100-plant threshold in the statute, since *male* plants contain substantially lower quantities of the psychoactive THC, and since the district court found that Proyect manufactured only 55 female plants, if male plants were excluded, then the mandatory minimum sentence would not apply. *Id.* At 88. Circuit Judge, George Pratt, rejected this argument, "We join our sister circuits that have held that

congress did not intend courts to count only female marijuana plants when determining a defendant's responsibility for drug quantities under § 841(b)(1)(B)(vii). Essentially, congress requires courts to perform this task by applying the simple concept that 'a plant is a plant is a plant.' Thus, the statute is clear." *Id.* at 88. Justice Pratt, relying on other circuit court decisions, further held that "Congress intended to outlaw all plants popularly known as marijuana to the extent that those plants possess THC." *Id.* at 89.

Conclusion

Since two independent chemical analyses revealed that Dixie X contained THC, and the product was meant for human consumption, and not least because the Defendants have utterly failed to establish that Dixie X fell outside the dictates of the CSA in 2012, the Court should deny the Defendant's Motion To Reconsider. It is worth mentioning in conclusion that Defendants argued earlier in the litigation that the amount of THC in Dixie X was permitted "according to Section 7606 of the Farm Bill (sic)." See ECF 61-14 at page 25. The product was sold in 2012, before the Farm Bill was enacted (in 2014), and was subject to 21 CFR 1308 *et seq.* in effect at the time. Where a Defendant cannot correctly identify the law in effect during the relevant time period, it is hard to imagine they could have adhered to such law.

Dated: September 13, 2019
New York, New York

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